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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,355	05/12/2008	Lawrence Solomon	ABT-054	2979

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EXAMINER	
VU, JAKE MINH	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
12/19/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,355	SOLOMON ET AL.	
	Examiner	Art Unit	
	JAKE VU	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *53,61,67,68,76 and 77* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *53,61,67,68,76 and 77* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed on 12/05/2011.

- Claims 53, 67 and 687 have been amended.
- Claims 53, 61, 67-68, 76-77 are pending in the instant application.

Claim Objections

Claim 67 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 67 recites “said dosage form comprising a separation mark positioned parallel to a vertical axis of the dosage form" and is dependent on claim 53, which recites "a score greater than 50% through the maximum height of sad first bottom layer", wherein this recitation from claim 53 has to be "a separation mark positioned parallel to a vertical axis of the dosage form”.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 53, 61, 67-68, 76-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention, ***are withdrawn*** in view of Applicant's Amendment and Clarification.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 53 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 recites "immediate release composition substantially free of drug". It's unclear what is being immediately released. Please clarify.

Claim 61 recites controlled-release composition, such as delayed release and quick dissolve oral or buccal release, wherein "quick dissolve oral or buccal release" seems to read more on immediate release.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 53, 61, 67, 76 are rejected under 35 U.S.C. 102(b) as being anticipate by HESS et al (CH 648754; machine translation provided by Applicant).

Applicant's claims are directed to a composition comprising of: a first bottom layer containing a drug and a score greater than 50% through the maximum height of said first bottom layer; and a second unscored top layer contacting said first layer substantially free of drug. Additional limitations include: controlled release, such as sustained-release; separation mark positioned parallel to a vertical axis of the dosage form; covered with an inert inactive composition.

HESS teaches a composition comprised of: a first bottom layer containing a drug and a score greater than 50% through the maximum height of said first bottom layer (see Figure 1a, wherein the drug is in S1); and a second unscored top layer contacting said first layer is a placebo (see Figure 1a; and page 3 under Fig 1), which reads on substantially free of drug. Additional limitations include: controlled release, such as slow release (see abstract), which reads on sustained-release; separation mark positioned parallel to a vertical axis of the dosage form (see Fig. 1); covered with an inert inactive composition, such as a placebo.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 53, 61, 67-68, 76-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over HESS et al (CH 648754; machine translation provided by Applicant) in view of MEDRI (US 4,789,546) and SASMAL et al (US 2005/0026992).

As discussed above, HESS teaches a composition comprised of: a first bottom layer containing a drug and a score greater than 50% through the maximum height of said first bottom layer (see Figure 1a, wherein the drug is in S1); and a second unscored top layer contacting said first layer is a placebo (see Figure 1a; and page 3 under Fig 1), which reads on substantially free of drug. Additional limitations include: controlled release, such as slow release (see abstract), which reads on sustained-release; separation mark positioned parallel to a vertical axis of the dosage form (see Fig. 1); covered with an inert inactive composition, such as a placebo.

HESS does not teach using a colorant for visually distinguishing said layer from another layer; or using a capsule.

MEDRI teaches the prior art had known of using different colorants, such as colored dyes (see col. 1, line 31), in different layers of a multiple-layer tablet to enable a patient to identify the tablet (see abstract).

SASMAL teaches a capsule composition comprised of minitablets that can be film coated (see [0043]; and [0053])), wherein the composition promotes patient compliance by avoiding inconvenience of taking multiple doses of medicines (see (0006]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate a colorant for visually distinguishing said layer from

another layer. The person of ordinary skill in the art would have been motivated to make those modifications, because it would enable a patient to identify the tablet, and reasonably would have expected success because the references are in the same field of endeavor, such as pharmaceutical drugs.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate using a capsule to put the tablets in. The person of ordinary skill in the art would have been motivated to make those modifications, because it would promote patient compliance by avoiding inconvenience of taking multiple doses of medicines, and reasonably would have expected success because the references are in the same field of endeavor, such as pharmaceutical drugs.

Response to Arguments

Applicant argues that the Hess reference describes a tablet which is scored from a top punch, or a top and a bottom punch - but not a bottom punch only.

The Examiner finds this argument unpersuasive, because the features upon which applicant relies (i.e., bottom punch only) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618